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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,700	04/21/2004	Chih-Chiang Yang	P464.312-0001	5387

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,700	Applicant(s) YANG ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 5/8/2008 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 7 and 15 have been canceled.
2. Claims 6 and 14 have been amended.
3. Remarks drawn to rejections under 35 USC 103(a).

Claims 1-6, 8-14 and 16-19 are pending in the case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 1-6, 8-14 and 16-19 under 35 U.S.C. 103(a) as being unpatentable over Vyas et al (International Journal of Pharmaceutics, 1998, 172, 33-70) in view of Pitha (US 4,727,064) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that:

1. Prior attempts to combine steroid-containing niosomes such as those of Vyas with cyclodextrin have failed. This is also shown by several publications including Ohvo and Slotte, Atger and Nishijo (references provided by applicants in support of their arguments).

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2. According to these publications addition of cyclodextrin to steroid-containing niosome resulted in the removal of the steroid compounds from the lipid bi-layer of the niosome, thereby disrupting the niosome structure instead of forming a stable structure.

Applicants' arguments and the references provided have been considered but are not found to be persuasive.

The failure of the prior attempts is in situations wherein the combinations were done differently. Slotte et al teach desorption of cholesterol from a combination of cholesterol in a phosphatidylcholine monolayer to which the cyclodextrin was separately added. Similar result is also taught by Nishijo and Atger. In these teachings the steroid is in combination with the lipid or liposome and addition of the cyclodextrin causes the release of the steroid from the lipid layer. This is expected since cyclodextrin is known to form a stable complex with several drugs via entrapment of the drug, in this case, the steroid, in its cavity. This is more likely to happen depending on the polarity of the steroid and the substituents on the cyclodextrin (see Slotte, et al, Abstract). One of skill in the art on reading the teaching of the references above will recognize that adding cyclodextrin to a preformed mixture of a steroid and lipid bi-layer causes the steroid to leak out and would not make an initial mixture of a steroidal compound with a lipid to form a niosome and then add the cyclodextrin to this mixture. Therefore, one of skill in the art will form a complex of the cyclodextrin and the steroidal compound first (this is a logical variant) and then use the surfactant to form the niosome. This way the steroidal compound or any drug can be transported across the stratum corneum by the niosome without disruption. Once it is transported there can be slow release of the steroid or drug from the cyclodextrin cavity. This is also well known to one of skill in the art and also in the field of cyclodextrins. The teachings in the

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references above, provided by the applicants, do not show the extensive leakage of the steroid from a steroid/cyclodextrin complex when the preformed complex is combined with a vesicle formed by a non-ionic surfactant.

Conclusion

Claims 1-6, 8-14 and 16-19 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623

GK